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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/457,173	12/08/1999	JAMES D. JACOBSON	JACOB100	7379
7590	05/03/2005		EXAMINER	
BRADFORD R L PRICE BAXTER HEALTHCARE CORPORATION FENWAL DIVISION RT 120 & WILSON ROAD ROUND LAKE, IL 60073			MENON, KRISHNAN S	
			ART UNIT	PAPER NUMBER
			1723	
			DATE MAILED: 05/03/2005	

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/457,173	JACOBSON, JAMES D.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Krishnan S. Menon	1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 23 March 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-5, 14, 16-30 and 102 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-5, 14, 16-30 and 102 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____.   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____.                                   |

## DETAILED ACTION

Claims 1-5, 14, 16-30 and 102 are pending after the amendment of 3/23/05

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-4, 16-18, 22-26 and 102 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,872,888 (Ehrfeld et al.).

Ehrfeld et al teach a monolithic polymeric filter membrane having a polymeric filter layer (62) including micron- scale precision shaped pores (81) and a polymeric support layer (61, 63) including a precision shaped porous support structure for the filter layer wherein given example of polymer is polymethyl methacrylate (PMMA) which changes under the influence of high energy e.g., X-ray, radiation, the support layer (61, 63) is substantially coextensive with the filter layer (62), the height of the support layer is a multiple of the thickness of membrane filter layer (62), pores are connected from opposite side of a single film and pore size of the membrane filter layer (62) is 0.2 micron to 2 microns (see figures 7-94 col. 2, lines 9-38, col. 3, line 55 - col. 4, line 40) (claims 1-4, 17-18, 22-26, 102).

With respect to the recitation added by amendment on 3/23/05, 'second material same as or sufficiently similar to' and 'line of distinction ... not reasonably discernable',

these limitations have no patentable weight because same material with no discernable line of distinction would not make any distinguishing, unanticipated and non-obvious structural difference compared to the prior art.

Regarding claim 16, the recitation of "the filter and support layer are formed separately of the same material and joined together to form the monolithic membrane" is not given patentable weight to the structure of the membrane because the membrane of Ehrfeld et al is a monolithic polymer filter membrane and is not distinguishable from the claimed membrane.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 5, 14, 21 and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ehrfeld et al as applied to claim 1 above, and further in view of U.S. Patent No. 5,753,014 (Van Rijn).

Ehrfeld et al teach a monolithic polymer filter membrane as described in above paragraph 1. Claim 5 essentially differs from the membrane filter of Ehrfeld et al in reciting that the support layer includes at least two sub-layers, a first sub-layer of a selected porosity and a second layer of different porosity than the first sub-layer and

disposed between the first sub-layer and the filter layer. Van Rijn teaches a membrane filter comprising a polymeric filter layer made of polyamide (etchable and photosensitive) including etched micron-scaled precision shaped pores of square, circular, or elongated cross section and a polymeric support layer made including multiple support layers with different pore sizes wherein the support layer is thicker than the filter layer, pore size ranges from 5 nanometers to 50 microns and filter layer is used to remove leukocytes (see figures 1, 9-15b, 25-29, 3 1-344 col. 1, line 57 - col. 9, line 5,, col. 11, line 22 - col. 13, line 14). Van Rijn teaches a filter comprising membrane layer (46), a molecular sieve layer (50) and a support layer (45) in sequence for gas separating capability (see figure 29; col. 10, lines 23-62) and further teaches filtration membrane with three mutually connected channel with pore sizes 0.5 micron, 1.5 micron and 5 micron for sorting particles on size (see col. 10, line 63 - col. 11, line 21). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a second sublayer of different porosity disposed between the first sublayer and the filter layer in the membrane filter of Ehrfeld et al for separating gas or sorting particles as suggested by Van Rijn.

Regarding claim 14, Van Rijn teaches the use of various polymeric materials for filter and support layers which are joined to form the filter membrane with polymeric bonding material (see col. 3, line 7 - col. 4, line 74 col. 5, lines 4-34). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the filter and support layer made of different materials that are sufficiently compatible to form a monolithic membrane.

Regarding claim 21, Van Rijn teaches a flexible filter layer, which requires a support to strengthen the filter (see col. 3, lines 7- 44). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to form a flexible filter membrane layer with appropriate support to strengthen the filter membrane under stress.

Regarding claim 27, Van Rijn teaches that the pore size of the membrane filter is between 5 nm and 50 microns (see abstract). It is well known in the art that the membrane filter with pore size less than or equal to about 0.08 microns is used in ultrafiltration application. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include membrane filter having pore size less than or equal to about 0.08 microns for ultrafiltration application.

Regarding claims 28-30, Ehrfeld et al teach that micropores are made by X-ray radiation through X-ray mask in a pattern corresponding to the distribution and cross-section configuration of micropores (see col. 3, line 67 - col. 4, line 2). Van Rijn teaches that other shapes for the cross-section of the perforation in the membrane may be chosen depending on the application including a strongly elongated or channel like shape for a potential high flow rate (see col. 8, lines 5-10) and the membrane may be used as a leucocyte filter, separating leucocytes from erythrocytes and or blood platelets (see col. 13, lines 3-6). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include an elongated cross sectional shaped pores in the membrane filter of Ehrfeld et al for application in high flow rate filtration as well as filtering leucocytes as suggested by Van Rijn.

3. Claims 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ehrfeld et al as applied to claim 1 above, and further in view of U.S. Patent No. 5,807,406 (Brauker et al).

Claims 19-20 essentially differ from the apparatus of Ehrfeld et al in reciting that polymeric material of filter layer and support layer is an etchable or photosensitive polyimide material. Ehrfeld et al teach that a membrane layer and support layer is made of polymeric material including PMMA which changes under the influence of high energy, e.g. X-ray, radiation (see col. 3, line 51-544 col. 4, lines 34-40). Brauker et al teaches a porous microfabricated polymer membrane structure made of etchable or photosensitive polyimide (see abstract). It would have been obvious to a person of ordinary skill in the art to substitute polyimide for PMMA of Ehrfeld et al as a filter and a support layer since these materials are in a similar class of polymer and possessing characteristics of being etchable or photosensitive.

#### *Response to Arguments*

Applicant's arguments filed 3/23/05 have been fully considered but they are not persuasive. The response to the arguments is given in the rejection.

#### *Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S. Menon whose telephone number is 571-272-1143. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on 571-272-1151. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit: 1723

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Patent Examiner  
4/18/05

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